REMARKS/ARGUMENTS

35 U.S.C. § 103 Rejection

In response to the Examiner's rejection of claims 21, 23, 26-29, and 33-37 as being obvious over Tankovich in view of Kye and Ho and of claims 24-25 as being obvious over Tankovich in view of Kye, Ho, and Obagi, the Applicant respectfully traverses.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. to modify the reference or to combine reference teachings. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones. 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); MPEP 2143.01. Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); MPEP 2143.02. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. In re Royka. 496 F.2d 981, 180 USPQ 580 (CCPA 1974); MPEP 2143.03. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 706.02(f) and 2143.

Accordingly, to support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). See also MPEP 706.02(j). However, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re. Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Further, it is impermissible to use the claimed invention as an instruction manual or template to piece together the teachings of the prior art so that the claimed invention is rendered obvious: "Joine cannot use

hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). See also MPEP 2143.01.

In the rejection of claims 21, 23, 26-29, and 33-37 under 35 U.S.C. § 103(a) as being unpatentable over Tankovich in view of Ho and Kye the Examiner has relied upon Tankovich as the principal reference and states that Tankovich teaches the claimed process except for the pretreatment and post-treatment with retinoic acid. The Examiner relies on Ho and Kye to supply the pretreatment and post-treatment steps. However, Ho and Kye use retinoic acid to reduce hyperpigmentation associated with ablative laser light treatment of the skin to treat sears. The Tankovich method utilizes nonablative exploding particles to produce sustained skin rejuvenation, and neither the exploding particles nor the laser light used to explode the particles cause hyperpigmentation. Applicant's process is used to produce sustained skin rejuvenation and not to remove sears. It is the combination of exploding particles and topical retinoic acid application that produces sustained skin rejuvenation, since each process independently is ineffective.

The applicant's invention is a method and process for producing sustained rejuvenation of the skin by combining the effects of exploding particles on the skin with the topical effects of a retinoic acid. The applicant's method is not a method for treating the skin with laser light. The laser light used in applicant's method has no effect on the skin. The laser light in applicant's method is used to make the particles explode. Consequently, applicant's method is not a laser treatment of the skin. The exploding of particles on the skin is not equivalent to using laser light to treat the skin.

The methods described in Tankovich (6050990) that use exploding particles are also not methods of laser treatment of the skin. They are methods of using exploding particles to treat the skin using laser light to explode the particles. This laser light has no effect on the skin. There is no method described in Tankovich for producing sustained rejuvenation of the skin. The references to skin rejuvenation in Tankovich refer to "skin peels" in which layers of the epidermis are removed (see col. 23, lines 29-31; col. 28, lines 23-27; and col. 52, lines 18-22). As noted in applicant's specification (page 2, lines 19-21) the skin peeling method of Tankovich

does not produce successful sustained rejuvenation of the skin. This is because excessive heat from laser light or exploding particles can cause severe burns, infection, and permanent scarring (see specification, page 1, lines 16-19). Hair removal is not equivalent to rejuvenation of the skin. Tankovich refers to these endpoints in the alternative "rejuvenation or hair removal" (see col. 23, lines 30-31; col. 25, lines 3-4; col. 50, line 63; and col. 51, lines 3-4). Rejuvenation of the skin is characterized by increased thickness and targor of the skin, while wrinkles and lines are reduced (see specification, page 7, lines 20-25 and page 8, lines 1-3). All of these effects make the skin appear smooth. Hair removal by the Tankovich method does not do this. Even though the hair can be removed by the Tankovich method, features such as skin thickness and targor, wrinkles, etc. are not affected. Nowhere in Tankovich is there a reference to "smooth skin" related to these methods.

The methods of Ho and Kye are for laser treatment of the skin for facial sears and are not useful for producing sustained rejuvenation of the skin because they are ablative, removing the epidermis, more so than in skin peeling. There is no disclosure of exploding particles with laser light in Ho or Kye. The retinoic acid used in Ho or Kye does not produce rejuvenation of the skin. The combination of Ho and Kye with Tankovich does not suggest or teach applicant's invention as claimed in amended claim 21 because the combination of Ho and Kye with Tankovich does not teach nor suggest combining retinoic acid with the application of exploding particles. As noted above, the exploding of particles of the skin is not equivalent to heating the skin with laser light. Neither exploding particles which are non-ablative, leaving the epidermis intact, nor 0.5% retinoic acid produce any sustained rejuvenation of the skin when used separately from each other.

There is no common practice of using retinoic acid for pretreatment or post-treatment with exploding particles on the skin. The Examiner states that Ho and Kye establish the state of the art for the use of retinoic as part of the pre-laser and post-laser regiment to reduce hyperpigmentation after laser resurfacing. The Examiner concludes that a skilled artisan would have been motivated to use retinoic acid to help reduce hyperpigmentation that occurs with laser treatment. However, applicant's method does not use a laser treatment for resurfacing of the skin. Applicant's method uses exploding particles to treat the skin and the exploding particles do

not cause hyperpigmentation. The laser light used by applicant's method to explode the particles also does not cause hyperpigmentation. Thus, there would be no reason or suggestion, or motivation from Key or Ho for a skilled artisan to use retinoic acid with the exploding particle method of Tankovich utilized by applicant.

In this regard, applicant discovered an unexpected synergism between non-ablative exploding particles and retinoic acid. An effect is synergistic when the effect of the combination of two procedures is greater than the sum of the individual effects of each procedure. Since the individual effects of non-ablative exploding particles on sustained skin rejuvenation is essentially zero, as is well known in the art, and since the effect of topical retinoic acid applied 4 to 16 times per month on sustained skin rejuvenation is essentially zero, as is well known in the art, the observations by the applicant of a clearly visible occurrence of sustained skin rejuvenation by the combination of nonablative exploding particles and topical retinoic acid is evidence of this synergism.

Although Ho and Kye teach that pretreatments and post-treatments can be performed with ablative laser treatment of the skin, this does not suggest or produce any motivation to use retinoic acid by itself for pretreatment or post-treatment in applicant's invention. There are a large number of substances that one could attempt to use for pretreatment and post-treatment, but there is no way for one of ordinary skill in the art to know which substance to use, without additional information such as that a given substance is useful with nonablative exploding particles, or that a given substance produces a consistent sustained rejuvenation of the skin at non-toxic doses. In Ho and Kye, the laser treatment of the skin is effective without retinoic acid and the effects of retinoic acid on hyperpigmentation described in Ho and Kye can occur in the absence of laser treatment of the skin. Thus, there is a basis for combining retinoic acid with laser treatment of the skin. There is no such basis for using exploding particle treatment of the skin in combination with retinoic acid to produce sustained skin rejuvenation. Consequently, there is no rational basis for combining the non-ablative exploding particle method of Tankovich with the ablative laser treatment of the skin of Ho and Kye in which retinoic acid is used in combination with the laser treatment to prevent hyperpigmentation. Thus, the applicant's

invention as claimed in amended claim 21 is not obvious in view of Tankovich in combination with Ho and Kye.

The Examiner has kindly pointed out that claim 21 does not recite that applicant's invention only requires one laser pass, that it does not recite the wavelength or the fluence of the laser light used to explode the particles, and that it does not exclude the process of removing skin. Claim 21 has been amended to recite a process for producing sustained rejuvenation of the skin and includes the limitations of one laser pass, the wavelength and fluence of the laser light used to explode the particles (contaminant), and that the process excludes the removing (ablation) of skin. As amended, claim 21 is not obvious over Tankovich in view of Ho and Kye. and is allowable. Claims 23, 24-29, and 33-37 are, thus, allowable as depending from an alfowable claim.

Support for the amendments to claim 21 are found in the specification on page 3, lines 8-9 and 13-14; page 4, lines 3-4; page 7, lines 3-21 (amended); page 9, lines 7-16; page 10, lines 10-13, and the abstract. The Examiner stated that there is insufficient antecedent basis for the limitation "the face" in claim 24, line 2. Claim 24 and 25 have been amended by replacing "the face" with "the skin of the face".

The amendments to the specification do not include new matter because they are limited to disclosures in Tankovich (U.S. Patent No. 6,036,684) which was incorporated by reference into the specification.

CONCLUSION

For the foregoing reasons Applicant respectfully requests that the Examiner reconsider the application in light of the amendments and that all claims in the application be permitted to proceed to allowance.

> Respectfully Submitted. Hefald M. Walsh

> Gerald M. Walsh, Ph.D. Reg. No. 34,946

Attorney for Applicant Phone: (205) 972-0145

Facsimile: (205) 972-0163